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附件

(54)名 稱：液態配物之注射器

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[57]申請專利範圍：

1. 一種供皮下或皮內注射有效成份之液態配物使用之手提式器具，其特點為一種組合，包含：一配物供給容器(3)；一適合與該容器(3)溝通之注射針(7)；用以經由注射針(7)使容器(3)放空之泵裝置(4、32、34、50)；用以將該器具固著於病人身體適當部位之固定裝置(16、17)；以及用以將注射針(7)插入病人皮膚之針驅動裝置(12、13)。
2. 根據申請專利範圍第1項之器具，其中流動控制裝置(20-25)。
3. 根據申請專利範圍第1項之器具，其中係成二部份(42、43)，一部份為可再使用，另一部份則可丟棄。
4. 根據申請專利範圍第3項之器具，其中可丟棄部份(42)包含供給容器(3)，而可再使用部份則包含用以驅動泵裝置(50)之裝置(51-54)。
5. 根據申請專利範圍第1項之器具，其中供給容器(3)係該器具上之一室，該室係由一隔片(4)所分開。
6. 根據申請專利範圍第1項之器具，其中供給容器(3)係風箱形式。
7. 根據申請專利範圍第1項之器具，其中供給容器(3)係可擠壓軟管形式。

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8. 根據申請專利範圍第1項之器具，其中供給容器(3)係柱塞注射器形式，其圓筒作用如供給容器。
9. 根據申請專利範圍第6、7或8項之器具，其中提供一種吸收材料以吸收有效成份。
10. 根據申請專利範圍第1項之器具，其中設有一個以上之供給容器。
11. 根據申請專利範圍第1項之器具，其中泵裝置包含一室，此室由一彈簧隔片與供給容器分開，並且其中設有壓力產生裝置。
12. 根據申請專利範圍第11項之器具，其中該室係予充填以推進劑蒸汽。
13. 根據申請專利範圍第11項之器具，其中該室內設有用以產生壓力之電化學、光化學或化學系統。
14. 根據申請專利範圍第11項之器具，其中該室內設有滲透或電滲透系統。
15. 根據申請專利範圍第1項之器具，其中泵裝置包含一機械驅動裝置。
16. 根據申請專利範圍第15項之器具，其中機械驅動裝置包含一彈簧、一雙金屬元件、一變形合金或一鐘錶機械驅動裝置。
17. 根據申請專利範圍第1項之器具，其中

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泵裝置包含一電或磁驅動裝置。

18. 根據申請專利範圍第17項之器具，其中一電泵或隔片泵或壓電泵包含一電磁鐵機構驅動裝置或一電磁鐵作為電或磁驅動裝置。
19. 根據申請專利範圍第1項之器具，其中固定裝置為一黏合劑層形式。
20. 根據申請專利範圍第1項之器具，其中固定裝置為一膏藥貼片。
21. 根據申請專利範圍第19或20項之器具，其中使用一種含有局部麻藥之黏合劑層。
22. 根據申請專利範圍第1項之器具，其中針之直徑小於0.05公厘。
23. 根據申請專利範圍第1項之器具，其中針驅動裝置係結合於一控制供給容器與針之間溝通之閥。
24. 根據申請專利範圍第16項之器具，其中

僅使用驅動彈簧之彈簧偏轉之一部份。

25. 根據申請專利範圍第1項之器具，其中設有用以控制泵裝置之電子控制裝置，該控制裝置有一供預設程式釋出分佈型之數據記憶器。
26. 根據申請專利範圍第1項之器具，其中泵裝置為一種可擠壓軟管泵形式，此泵為可變軟管剖面，並且此泵使釋出分佈型可設定程式。
27. 根據申請專利範圍第1項之器具，其中針驅動裝置係予設計為供0.5—5公厘之穿刺深度。
28. 根據申請專利範圍第1項之器具，其中容器係設有由隔片予以關閉之孔，並且容器係在使用前不久經由此等孔予以充填。
29. 根據申請專利範圍第1項之器具，其中結合於感測器以控制或改變釋出速率。

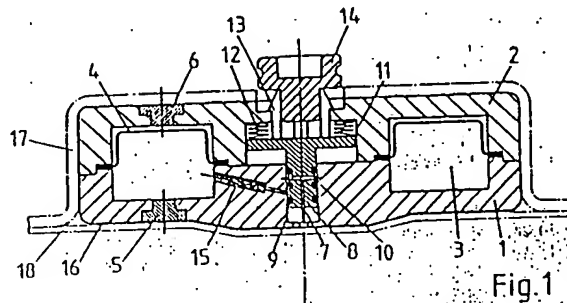


Fig. 1

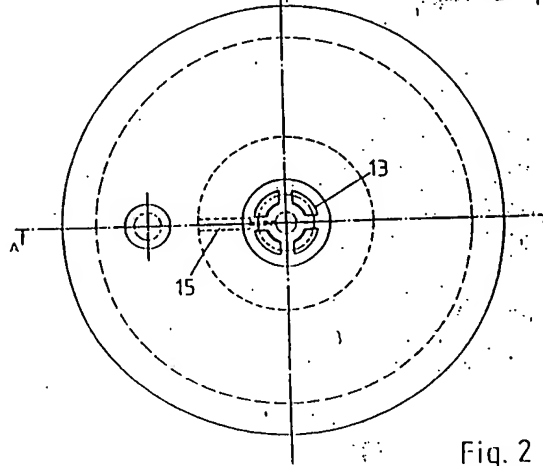


Fig. 2

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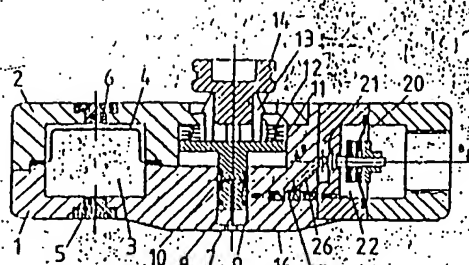


Fig. 3

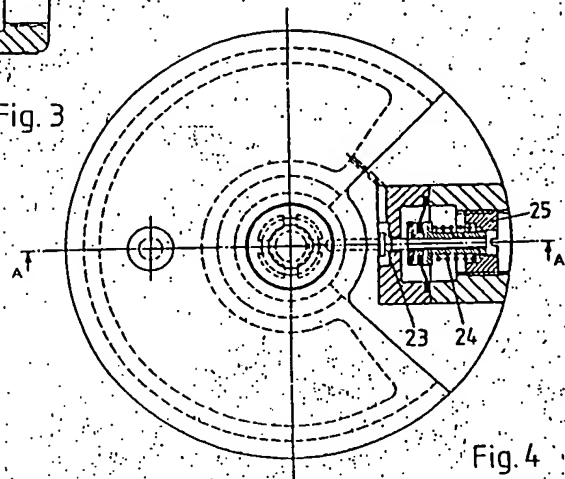


Fig. 4

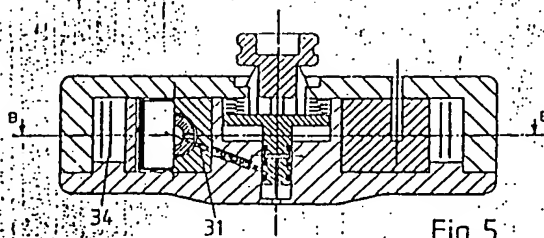


Fig. 5

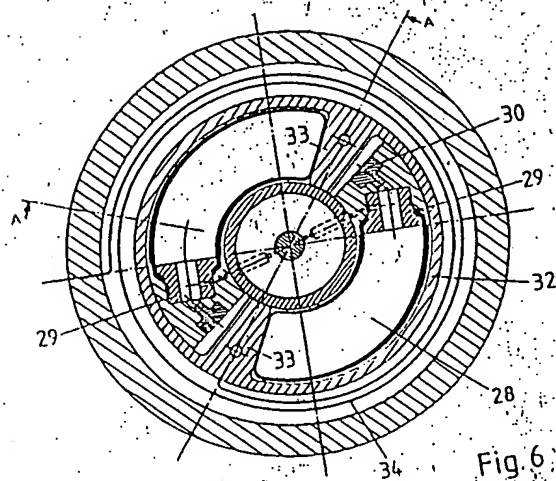
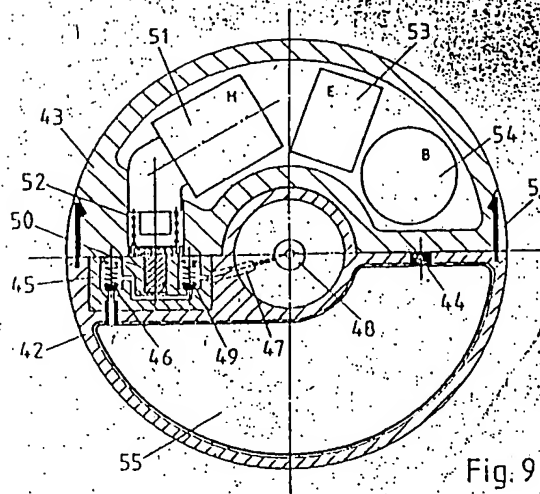
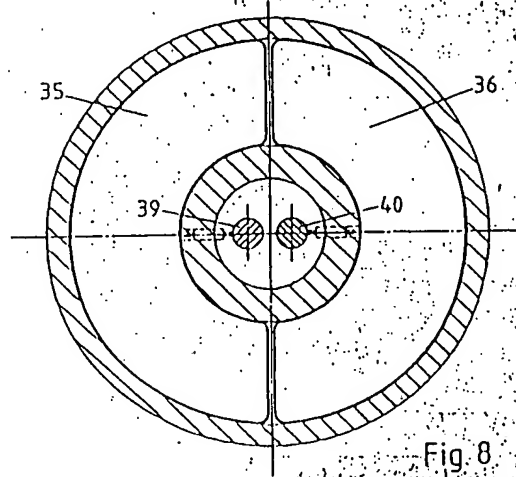
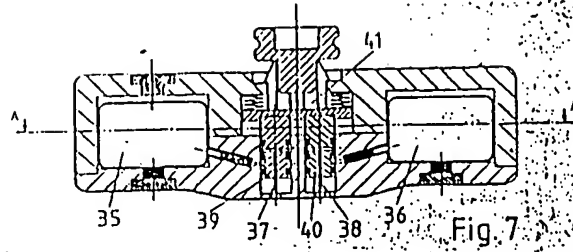


Fig. 6

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A B S T R A C T

The portable appliance is of use for the subcutaneous or intradermal injection of a liquid formulation of an active principle and it comprises in combination: a supply vessel (3) for the formulation; an injection needle (7) adapted to communicate with the vessel (3); pump means (4, 32, 34, 50) for emptying the vessel (3) through the injection needle (7); securing means (16, 17) for securing the appliance to an appropriate part of the patient's body; and needle-driving means (12, 13) for shooting the injection needle (7) into the patient's skin.

Fig. 1

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5 The invention relates to a portable appliance for the
subcutaneous or intradermal injection of a liquid
formulation of an active principle.

10 There has for some time past clearly been a need for
small, compact and portable injection appliances which can
be worn on a suitable part of the body and which provide a
preferably subcutaneous release of accurately defined
quantities of active principles into the body over prolonged
periods of time. Various devices of this kind having
15 considerable advantages over the conventional subcutaneous
syringe are already known. In conventional subcutaneous
injection a so-called bolus of an active principle is
introduced into the body and must be gradually absorbed and
distributed therein. Distribution depends to a considerable
20 extent upon the physiological circumstances of the
individual being treated and is therefore uncontrollable.
The advantage of appliances which release an active
principle continuously over a prolonged period of time is
that administration can be accurately controlled to suit the
25 body's requirements. Indeed, it is possible for phases of
release to alternate with phases of non-release. A
physiologically adapted release of this kind is advantageous
more particularly in the case of highly active agents such
as insulin, interferon or the like.

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Conventionally, known appliances of this kind have a
vessel which contains the active principle and with which an
injection needle communicates. Pump means discharge the
contents of the vessel into the body over a predetermined
35 period of time. DE-3 121 888 discloses an example of such an

appliance. It has a supply vessel in the form of a hose which a clockwork-driven squeezing roller empties through an injection needle connected to the end of the hose. The needle is introduced into the tissue some distance away from the appliance. The appliance can be worn or carried on the wrist like a wrist watch. An appliance of a different kind disclosed in US P 4 552 561 can be stuck to the skin and carries the injection needle on its underside so that the place where the needle penetrates the skin is covered while the appliance is in use. This appliance also needs the needle to pierce the tissue. It is more particularly the piercing of the tissue with the needle that is problematic in the case of conventional subcutaneous bolus injections and in the case of the more recent subcutaneous injection appliances hereinbefore referred to. People who are not experts in medicine are usually insufficiently practised to place such a needle correctly and they suffer from a completely justified fear of the likely pain.

It is the object of the invention to prepare a portable injection appliance of the kind hereinbefore set out which is free from the disadvantages of the known appliances and which can readily be used more particularly by persons not expert in medicine.

According to the invention, this is achieved by an appliance of the kind hereinbefore referred to which is distinguished by a combination comprising: a supply vessel for the formulation; an injection needle adapted to communicate with the vessel; pump means for emptying the vessel through the injection needle; securing means for securing the appliance to an appropriate part of the patient's body; and needle-driving means for shooting the injection needle into the patient's skin.

The appliance can also comprise flow control means enabling the release of active principle either to be kept

constant or to follow a predetermined profile.

According to another feature of the invention, the appliance is in two parts, the part containing the more
5 valuable elements being reusable while the other part can be discarded as an expendable item after being used once.

The vessel for the active principle or the solution thereof can quite simply be, for example, a part of the
10 appliance casing, in which case an appropriate diaphragm which is made of elastomers or metals or the like in single or multilayer form delimits a chamber. Another possibility for a supply vessel is a closed vessel also made of
15 elastomers or metals or the like, for example, in the form of bellows. The supply vessel can also take the form of a squeezable hose such as referred to by way of example in the introduction hereof. The vessel can also take the form of a
20 plunger syringe whose cylinder is operative as supply vessel. An absorbent material like a sponge can be used to take up the active principle. More than one separate supply
25 vessels or chambers or can be provided, for example, when two active principles have to be injected or when a lyophilisate of active principle and a reconstituting solvent are used. Various forms of energy can be considered
30 for driving the vessel-emptying pump means. For instance, the pump can be gas-operated, in which event the pressure necessary to empty the vessel can be produced by electrolysis or photolysis or chemical reactions and by propellant vapours such as Freon or the like. Another
35 possibility is to produce the requisite pressure by ordinary osmosis or electro-osmosis. Mechanical drives using, for example, springs or bimetallic elements or memory alloys or clockwork drives are of course another possibility. Electric or magnetic drives such as the known electric pumps, diaphragm pumps, piezoelectric pumps, electric clock drives or magnets can also be considered.

An adhesive layer on the patient-engaging surface of the appliance, such layer possibly extending as a plaster beyond the appliance, is more particularly suitable for securing the appliance to the appropriate part of the patient's body.
5 A possible alternative is a securing band or tape like the armband shown in the German Offenlegungsschrift hereinbefore mentioned.

The needle-driving device is preferably a metal spring.
10

For constant flow operation the active principle is arranged to be released constantly, for example, by means of capillaries or frits or diaphragms. Also, the flow can be adjusted by adaptation of the viscosity of the liquid
15 formulation of the active principle.

Control of the quantity of active principle released can also be embodied in various ways. For example, a squeezable hose whose diameter is increased or reduced to suit
20 requirements can be disposed between the supply vessel and the needle. Another possibility is to provide a pressure-reducing valve. Another possibility is to select a particular range of the expansion of the driving spring or to use special cup springs in which the force is constant
25 within limits over a distance. More elaborata flow control can be provided by feedback using sensors. Flow control can also be on the basis of a specially programmed pumping mechanism being used for the vessel-emptying operatione.

30 Very thin capillaries - i.e., capillaries having a diameter of preferably < 0.0 mm - are used as injection needles, since pain increases with needle thickness. The depth of penetration and the way in which the needle is ground also have a bearing on pain. Advantageously,
35 therefore, the penetration depth is at most 5 000 μ m. Also, the needle is preferably ground at an inclination, for example, like a lancet.

Even though needle diameter and penetration depth do not cause pain, the formulation itself may cause pain or irritation. This can be countered by a local anesthetic in the formulation.

5

Embodiments of the invention will be described hereinafter with reference to the accompanying drawings wherein:

10 Fig. 1 is a cross-section through an injection appliance according to the invention;

Fig. 2 is a plan view corresponding to Fig. 1;

Fig. 3 is a cross-section through another embodiment of the invention;

15 Fig. 4 is a plan view with partial sectioning of the appliance shown in Fig. 3;

Fig. 5 is a cross-section through another embodiment of the invention;

Fig. 6 is a section on the plane B-B of Fig. 5;

20 Fig. 7 is a cross-section through another embodiment of the invention;

Fig. 8 is a section on the plane A-A through the appliance of Fig. 7, and

25 Fig. 9 is a section through another embodiment of the invention on a plane perpendicular to the axis.

The appliance shown in Figs. 1 and 2 comprises a two-part flat cylindrical casing having a bottom part 1 and a top part 2. The two parts 1, 2 are rigidly interconnected, 30 for example, by screwthreading (not shown). Annular recesses in the contacting surfaces of the two parts 1, 2 together form an annular chamber 3. A diaphragm 4 subdivides the same into two separate chambers, both of which communicate with the exterior by way of filling orifices 5, 6 normally closed 35 by plugs.

An injection needle 7 and driving means for shooting the same are disposed at the centre of the discoid casing. The needle is a steel capillary of 200 μ m diameter.

Alternatively, a glass capillary could be used. A carrier 8 carries the needle 7. The carrier 8 has a bottom cylindrical part and a top flat discoid part. The cylindrical part is disposed for axial movement in a corresponding bore 9 in the casing bottom part 1 and is formed with a bore 10 which extends perpendicularly to its axis and which communicates with the interior of the needle 7. The cylindrical outside surface of the cylindrical part is formed with three peripheral grooves in which O-ring seals are introduced. There is also a shallow peripheral groove at the level of the bore 10.

In its bottom part the bore 9 reduces to a diameter just large enough for the needle to pass through.

The top discoid part of the needle carrier 8 is disposed for axial movement in a corresponding further concentric bore 11 of the casing top part 2. Over substantially two-thirds of the thickness of the part 2 the bore 11 reduces to substantially half its diameter so that an abutment is formed. Disposed between the same and the top part of the needle carrier 8 is a driving spring 12 for driving the needle into the patient's skin.

The needle carrier 8 also has resilient retaining fingers 13 which extend upwards from its surface and which have a pawl-like step or shoulder engaging the edge of a widening of the bore 11. When the fingers 13 are in the engaged state the carrier 8 with the needle 7 is in its top position in which the spring 12 is under stress and the needle does not project beyond the casing bottom surface.

Disposed between the fingers 13 is a safety cover or cap 14 which prevent accidental compression of the fingers 13.

likely to trigger the needle drive. The safety cover 14 is formed on its other side with a bore whose diameter is so adapted to appropriate inclined surfaces of the fingers 13 that the same are pressed together when the cap 14 is pressed on so that the retaining mechanism is released.

A communicating bore 15 is disposed in the casing bottom part between the bottom compartment of the chamber 3 and the bore 9. The same widens over some of its length to receive a restrictor element, such as a Teflon frit. The bore 15 so extends as to join the bore 9 at a height corresponding to the bore 10 in the needle carrier 8 when the same is in its bottom position. In the top end position the opening where the bore 15 joins the bore 9 is closed by the cylindrical part of the needle carrier 8 and by the bottom two O-rings.

The appliance has an adhesive layer 16 on its underside. The appliance is also embedded in a correspondingly shaped securing plaster 17. The layer 16 and the adhesive layer of the plaster are protected before use by a foil 18. The adhesive layer 16 on the underside and the adhesive layer of the plaster can contain additional substances such as a local anesthetic.

In production, after the appliance has been assembled the bottom compartment of the chamber 3 is filled with a required active principle by way of the aperture 5, whereafter the same is closed. Also, the top compartment of the chamber 3 is filled with a propellant through the aperture 6. These fillings are usually production operations and in that case are not carried out by the user. However, in the case of some active principles it may be convenient to carry out filling shortly before use. The appliance is then ready for use.

The appliance operates as follows:

The user removes the foil 18 and sticks the appliance 80 an appropriate part of his body by means of the plaster 17 and adhesive foil 16. The user then removes the safety cap 14, turns it and presses it onto the inclined surfaces of the fingers 13. The same are therefore compressed and
5 release the needle drive. The spring 12 expands and presses the needle carrier 8 with the needle 7 downwards through the predetermined distance and through the adhesive foil onto the user's skin. The needle should penetrate something like
10 at least 50 μm and at most approximately 5000 μm into the skin. The piercing of the skin by the needle is painless or nearly so because of the reduced depth of penetration, the small diameter of the needle and its inclined grinding.

15 Simultaneously as the needle carrier 8 descends the cross-bore 10 moves to the height of the opening of the communicating bore 15 so that the same communicates with the needle 7. The way is then open for the active principle to flow through the needle, the flow being determined by the
20 pressure of the propellant in the top compartment of the chamber 3 and by the restriction provided by the restrictor 15. The volume of the flow of active principle and, therefore, the duration of injection can be determined by appropriate choice of these factors.

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The appliance shown in Figs. 3 and 4 has the same storage vessel and the same needle-shooting device as the embodiment hereinbefore described. An additional feature, operative to compensate for variations in the pressure of
30 the propellant is a pressure-reducing valve. The same is disposed in a segment of the circular casing. Correspondingly, the chamber 3 extends around only some of the periphery.

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The reducing valve has its own casing which is received in a corresponding recess in the appliance casing. Internally the reducing valve is subdivided by a diaphragm.

20; in a manner conventional in pressure-reducing valves,
into a high-pressure chamber 21 and a low-pressure chamber
22. A ram 23 is disposed in the communicating bore between
the chambers 21 and 22, is secured to the diaphragm 20 at
5 its centre and can close the communicating orifice by moving
axially. A spring 24 is disposed on the other side of the
diaphragm between the ram 23 and an adjustable abutment 25.
The spring 24 basically determines the pressure in the
low-pressure chamber. The high- pressure chamber 21
10 communicates by way of a communicating bore 26 with the
bottom compartment of the chamber 3 - i.e., the reservoir of
active principle. The low-pressure chamber 22 communicates
by way of bore 27 with the central bore 9 and, as in the
embodiment hereinbefore described, opens out at the level of
15 the cross-bore 10 when the needle carrier is in its bottom
end position.

The pressure-reducing valve enables a substantially
constant release rate of active principle to be maintained
20 irrespective of pressure variations on the high-pressure
side. Such pressure variations may be caused by variations
in the vapour pressure of the propellant as a result of
temperature variations.

25 As in the previous example the appliance shown in Figs.
3 and 4 also has an adhesive layer, a securing plaster and a
protective foil and operates in virtually the same way as
the embodiment previously described.

30 In the embodiment shown in Figs. 5 and 6 an alternative
facility for conveying the active principle and a different
form of reservoir are provided. The reservoir is in the form
of two bags or bubbles or bellows 28 formed on one side with
an aperture via which they are secured to a mount 29 formed
35 with a filling aperture 30 and a bore 31 communicating with
the central bore 9. The two mounts 29 are rigidly connected
to the central cylindrical part of the casing bottom part 1.

A rotating member 32 is disposed around this stationary part and has two inwardly projecting webs 33 each engaging with the backs of the bags 28.

5 Between the member 32 and the outside wall of the casing top part 2 is a compartment receiving a spiral spring 34. The same is secured at one end in the casing wall and at its other end in the member 32. When the spiral spring 34 expands, it rotates the member 32, the webs thereof
10 compressing the bags 28 so that the active principle therein empties through the orifices 31.

By using just some of the usable number of turns of the spiral spring 34 to produce the rotary movements, a control
15 effect is achieved. Consequently, the driving spring is operative both to convey the active principle and to control flow. In other respects this embodiment operates similarly to the embodiment shown in Figs. 1 and 2.

20 In contrast to the embodiments so far described, the appliance shown in Figs. 7 and 8 has two supply vessels or chambers 35, 36 and two separate needle carriers 39, 40 which have needles 37, 38 and which a common activating mechanism 41 drives. This embodiment is of use when it is
25 required to inject two active principles simultaneously and separately.

As an alternative to the version shown, a single needle carrier having two needles could be provided instead of the
30 two needle carriers with two needles, in which event the sealing system would have to be more elaborate.

The embodiment shown in section in Fig. 9 has electrically driven conveyance of the active principle.
35 Because of the relatively high cost of the electrical elements of this embodiment the appliance is divided into a discardable part 42 and a reusable part 43. The two parts

42, 43 are interconnected by resilient clips 56 which engage in corresponding recesses.

5 The disposable part 42 comprises a supply vessel 55 with provision for filling closed by a partition 44. The system is such that the reservoir can, if required, be filled shortly before use. The disposable part 42 also comprises pump means 45 having an intake valve 46 communicating with the supply vessel, a delivery valve 49 controlling a line 47
10 to an injection needle 48, and a plunger pump 50 disposed between and connected to the two valves. The pump means 45 operate as follows: when the plunger of the pump 50 is drawn back from the position shown a predetermined volume is intaken through the intake valve 46 from the supply vessel.
15 The delivery valve 49 stays closed in this phase. When the piston makes its next advance, the intake valve 46 closes and the delivery valve 49 opens so that the intaken volume is supplied to the injection needle.

20 The injection needle together with the needle carrier and the piercing mechanism (not shown here) also forms part of the discardable part.

25 The more valuable reusable part 43 contains the electric drive for the pump means, in the form of an electromagnet 51 which draws the plunger of the pump 50 back, the plunger being advanced by a return spring 52. An electronic control facility 53 controls the electromagnet 51. A battery 54 provides power for the electromagnet 51 and the electronic
30 control 53.

An electrically driven pump is particularly suitable for combination with electronic control of the release quantity.
35 The release profile can, for example, be pre programmed and stored in some suitable way. The release rate can be checked by appropriate sensors.

In the embodiments shown the needle-driving means have been combined with the operation of the valve. These two operations can readily be separated so that, for example, first the needle is shot, whereafter a valve opens
5 separately. Skin-piercing movements other than simple injection perpendicularly to the skin surface are possible; for example, the vertical piercing movement can be coupled with rotation of the needle or the needle can be injected into the skin at an inclination to the skin surface.

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第 7610744^P 號專利申請案
中文申請專利範圍修正本(79年11月)

Chinese Patent Application No. 76107449
Amended Claims (November 1990)

1. A portable appliance for the subcutaneous or intradermal injection of a liquid formulation of an active principle,
5 characterised by a combination comprising: a supply vessel (3) for the formulation; an injection needle (7) adapted to communicate with the vessel (3); pump means (4, 32, 34, 50) for emptying the vessel (3) through the injection needle (7); securing means (16, 17) for securing the appliance to
10 an appropriate part of the patient's body; and needle-driving means (12, 13) for shooting the injection needle (7) into the patient's skin.
2. An appliance according to claim 1, characterised by flow
15 control means (20 - 25).
3. An appliance according to claim 1, wherein it is in two parts (42, 43), one of which is reusable and the other of which is discardable.
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4. An appliance according to claim 3, wherein the discardable part (42) comprises the supply vessel (3) and the reusable part comprises means (51 - 54) for driving the pump means (50).
25
5. An appliance according to claim 1, wherein the supply vessel (3) is a chamber in the appliance, the chamber being separated by a diaphragm (4).
- 30 6. An appliance according to claim 1 wherein the supply vessel (3) is in the form of bellows.
7. An appliance according to claim 1, wherein the supply vessel (3) is in the form of a squeezable hose.
35
8. An appliance according to claim 1, wherein the supply vessel (3) is in the form of a plunger syringe

whose cylinder is operative as supply vessel.

9. An appliance according to any of claims 6 - 8,
wherein an absorbent material is provided to
5 take up the active principle ..

10. An appliance according to claim 1, wherein
more than one supply vessel is provided.

10 11. An appliance according to claim 1, wherein
the pump means comprise a chamber which is separated from
the supply vessel by a resilient diaphragm and in which
pressure-producing means are provided.

15 12. An appliance according to claim 11, wherein
the chamber is filled with propellant vapour.

13. An appliance according to claim 11, wherein
an electrochemical, photochemical or chemical system
20 for producing a pressure is provided in the chamber.

14. An appliance according to claim 11, wherein
an osmosis or electro-osmosis system is provided in the
chamber.

25 15. An appliance according to claim 1, wherein
the pump means comprise a mechanical drive.

16. An appliance according to claim 15, wherein
30 the mechanical drive comprises a spring, a bimetallic
element, a memory alloy or a clockwork drive.

17. An appliance according to claim 1, wherein
the pump means comprise an electric or magnetic drive.
35

18. An appliance according to claim 17, wherein
an electric pump or diaphragm pump or piezoelectric

pump comprises an electric clock drive or an electromagnet as electric or magnetic drive.

19. An appliance according to claim 1, wherein
5 the securing means are in the form of an adhesive layer.

20. An appliance according to claim 1, wherein
the securing means comprise a plaster.

10 21. An appliance according to claim 19 or 20,
wherein an adhesive layer containing a local
anesthetic is used.

22. An appliance according to claim 1, wherein
15 the needle has a diameter of < 0.05 mm.

23. An appliance according to claim 1, wherein
the needle-driving means are combined with a valve
controlling communication between the supply vessel and the
20 needle.

24. An appliance according to claim 16, wherein
only a fraction of the spring deflection of a driving
spring is used.

25 25. An appliance according to claim 1, wherein
electronic control means for controlling the pump means are
provided the control means having a data memory for a
programmed release profile.

30 26. An appliance according to claim 1, wherein
the pump means are in the form of a squeezable hose pump
which is of variable hose cross-section and which enables
the release profile to be programmed.

35 27. An appliance according to claim 1, wherein
the needle driving means are designed for a penetration

depth of from 0.5 - 5 mm.

28. An appliance according to claim 1, wherein
the vessel is formed with apertures which are closed by a
partition and through which the vessel is filled shortly
5 before use.

29. An appliance according to claim 1, wherein
combination with sensors to control or vary the release rate.
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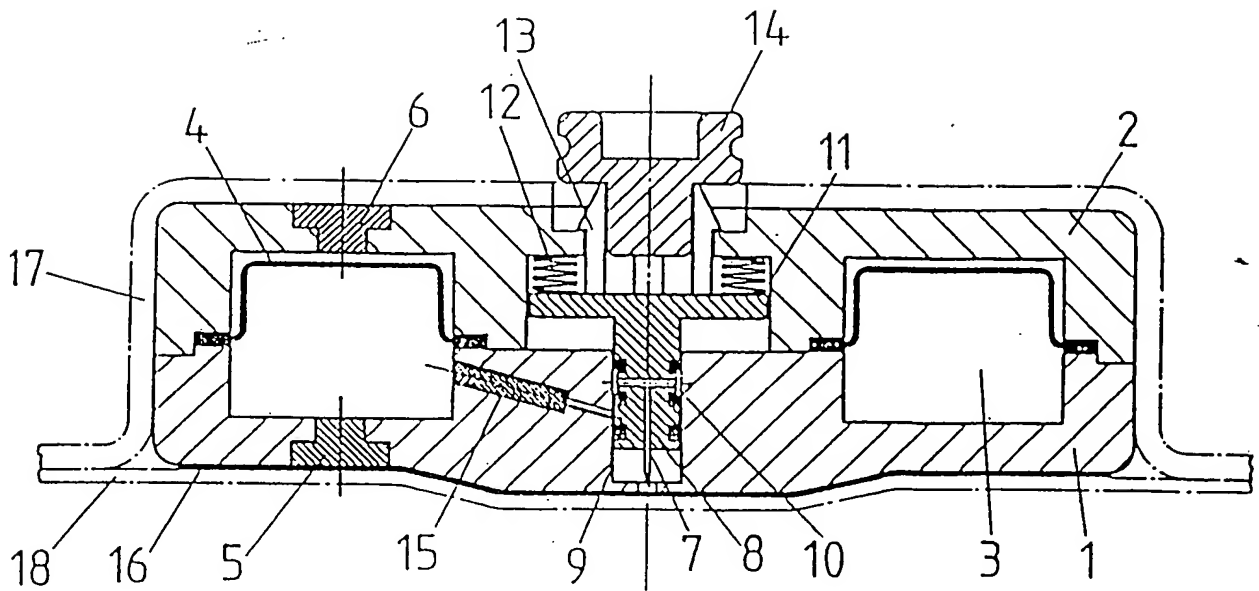


Fig. 1

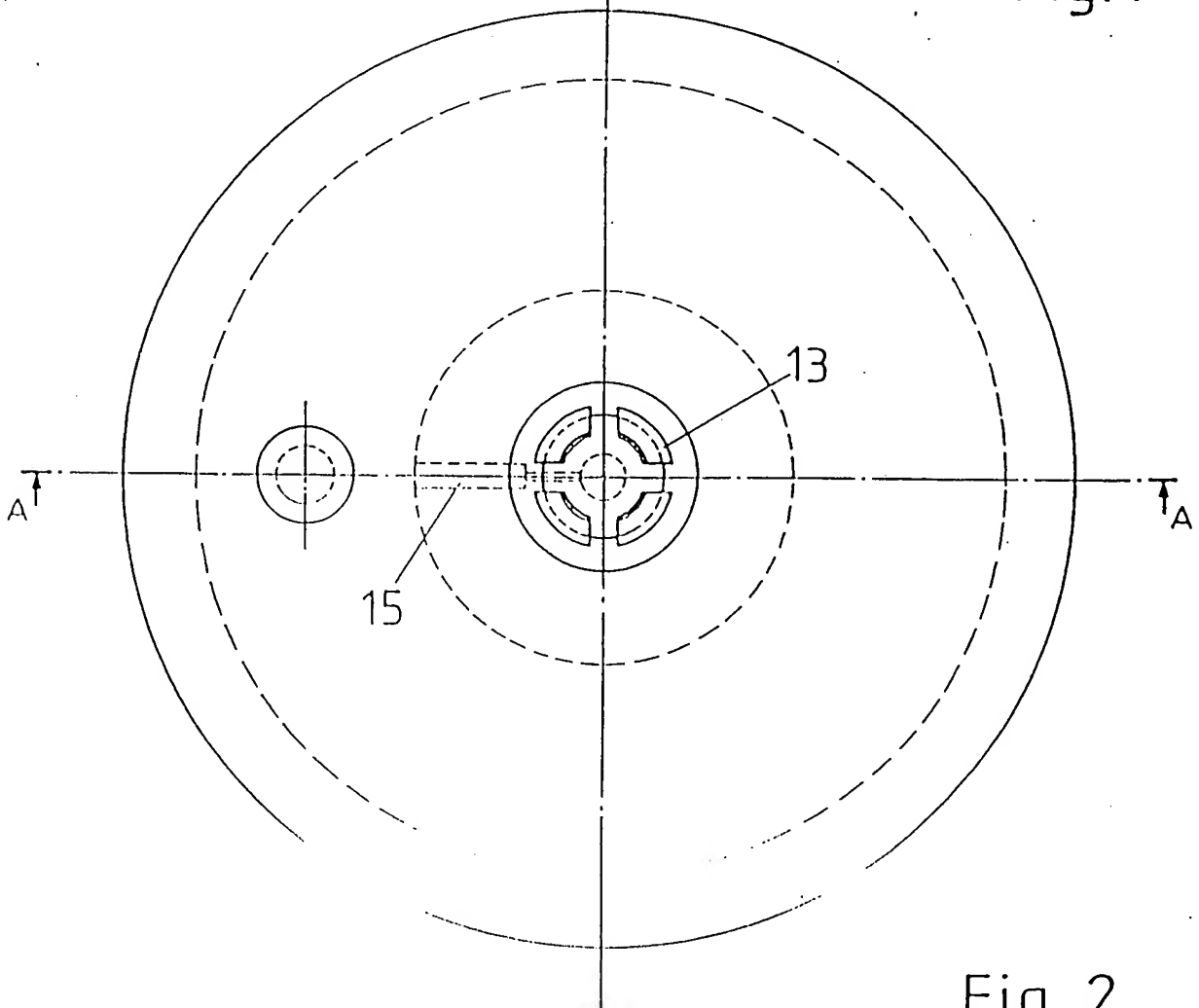


Fig. 2

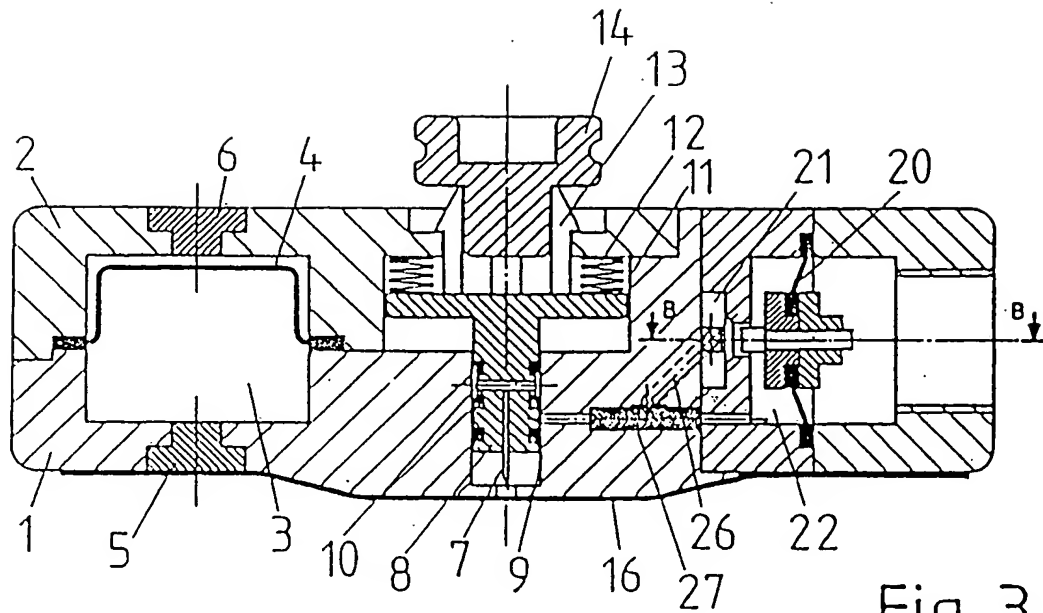


Fig. 3

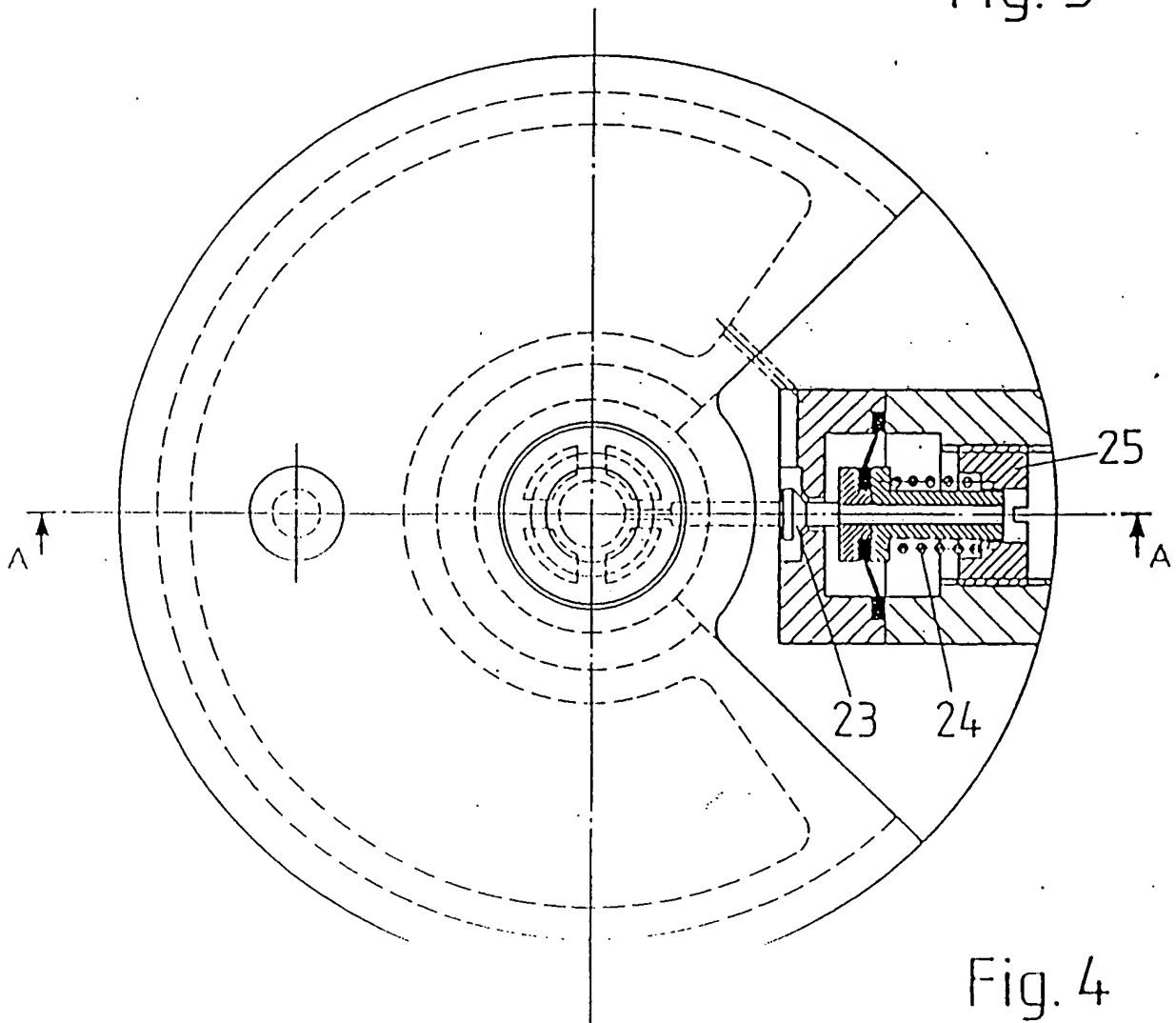


Fig. 4

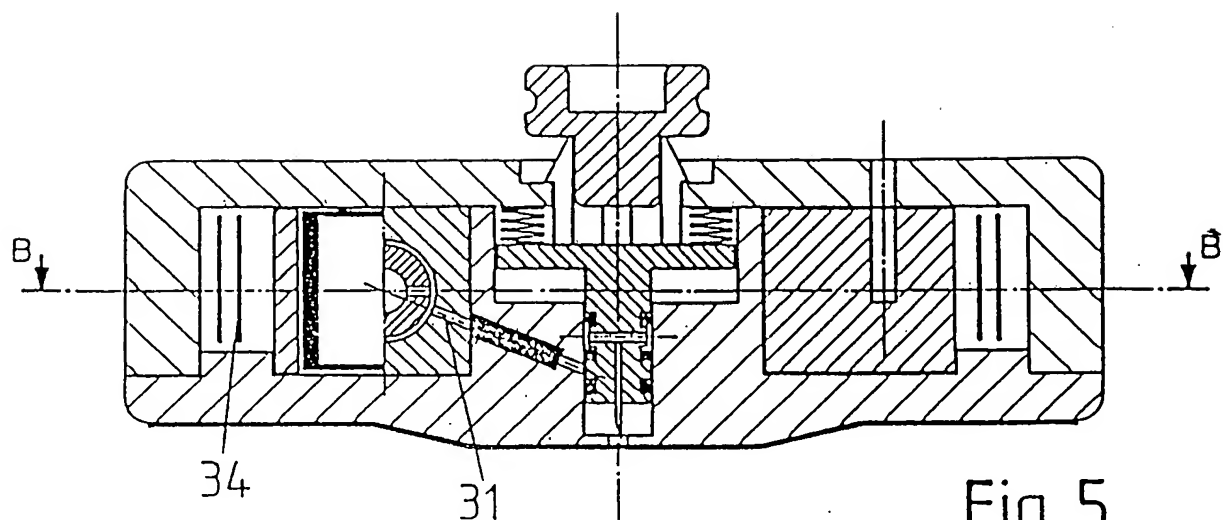


Fig. 5

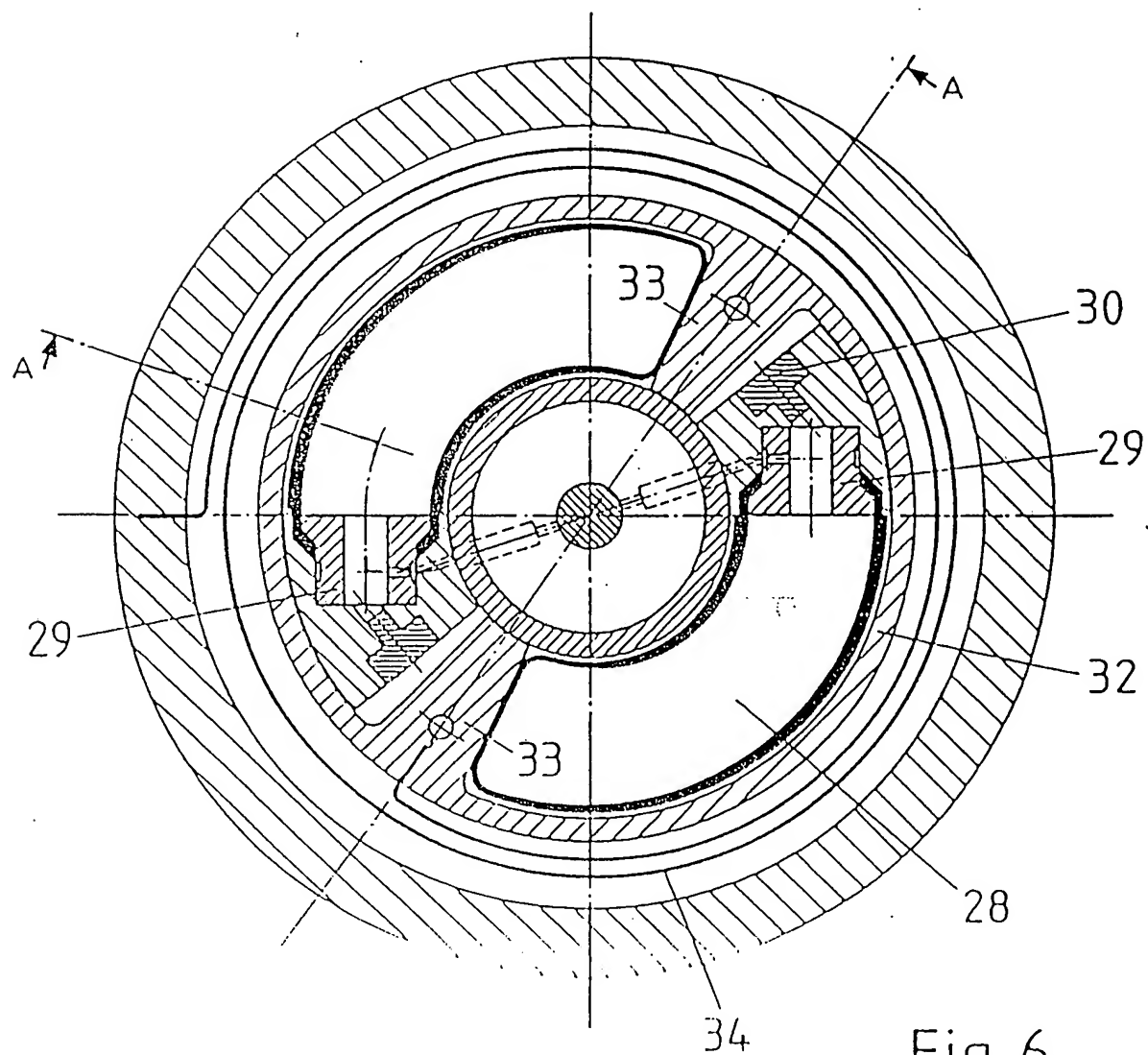
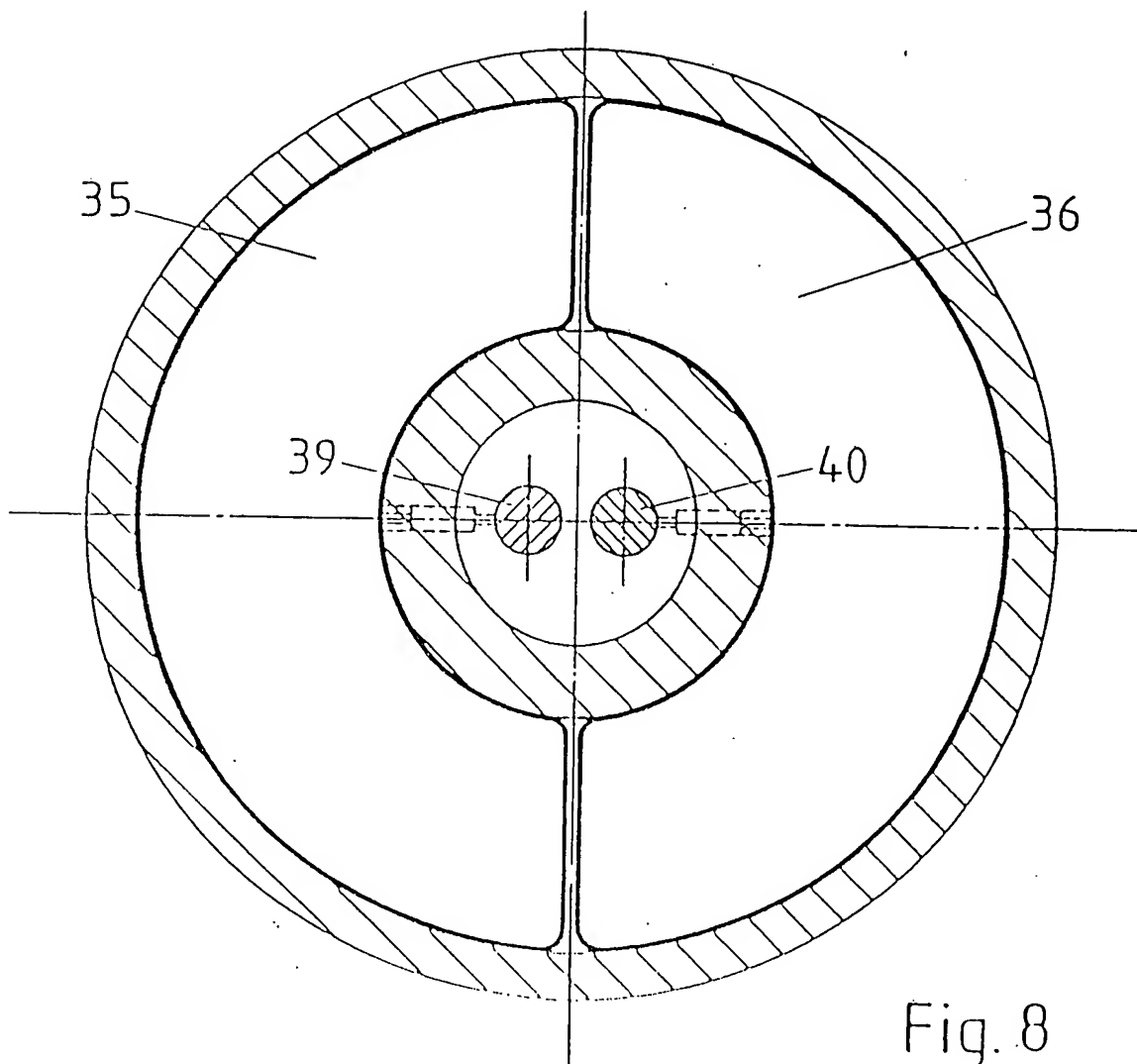
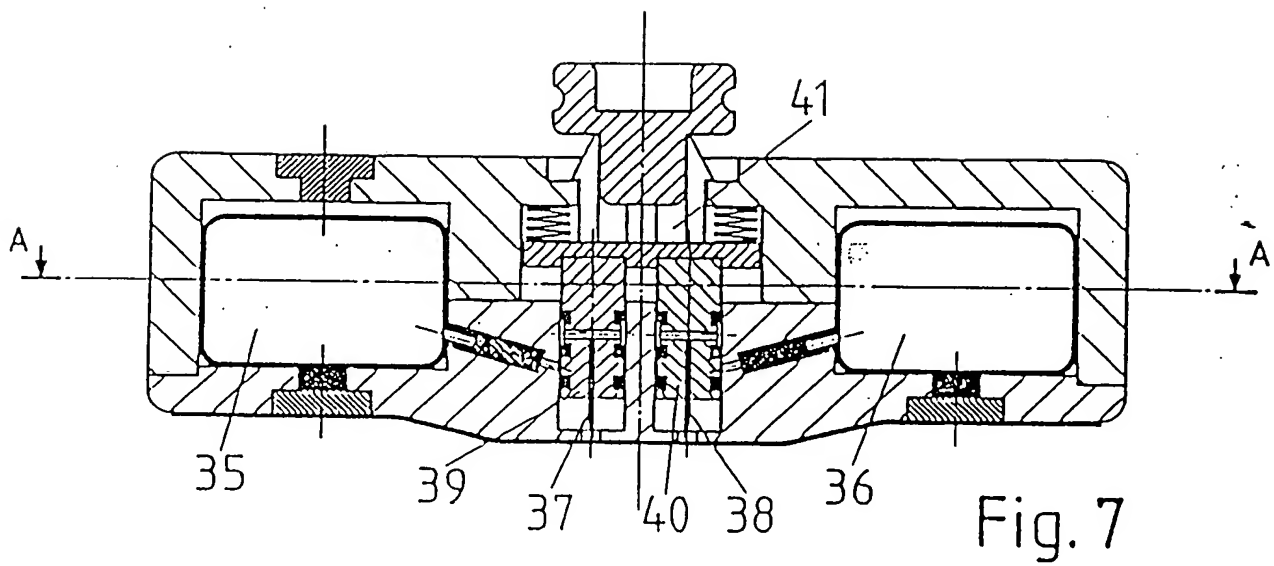


Fig. 6



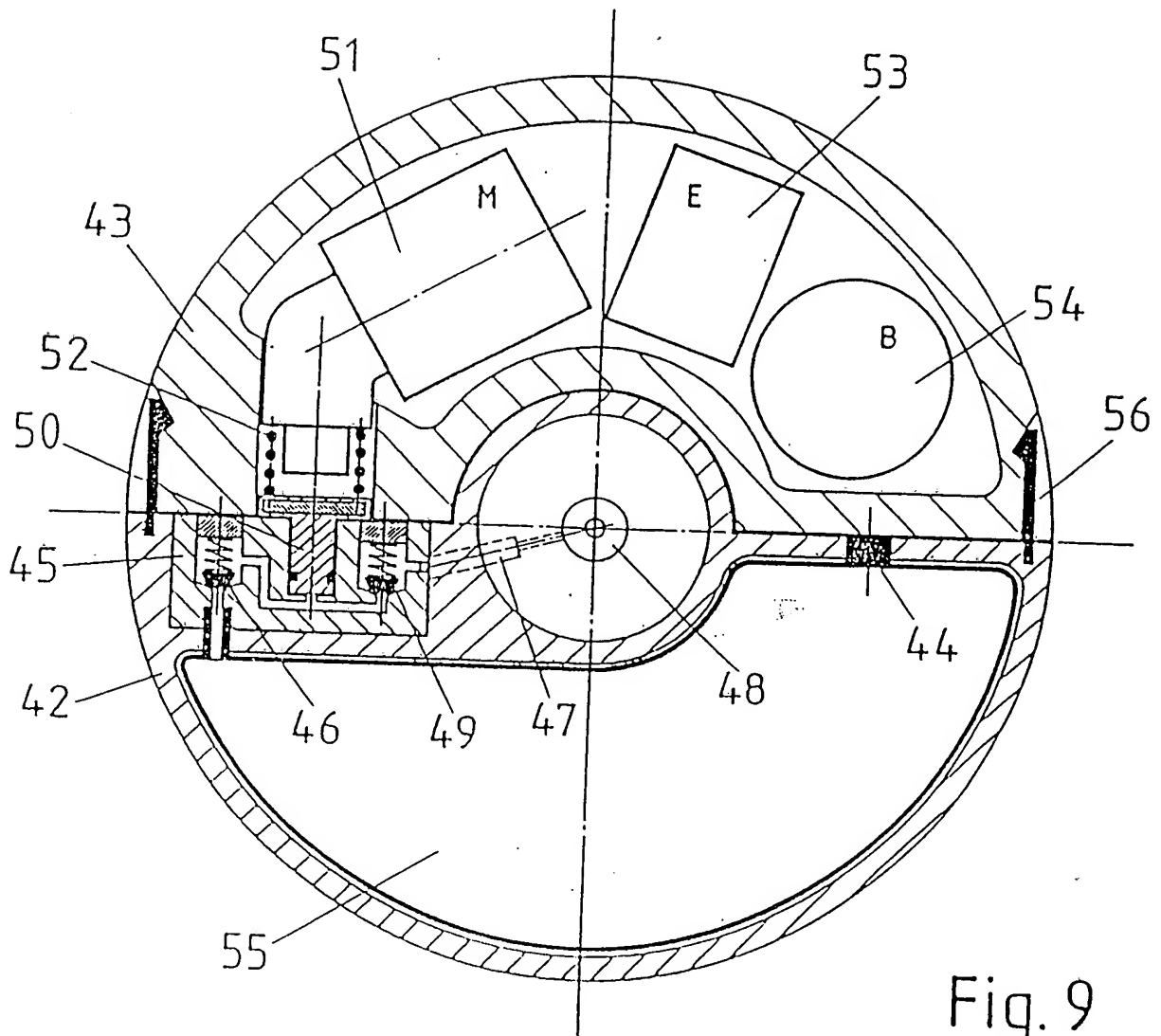


Fig. 9

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